

Amendment and Response

Serial No.: 09/507,108

Confirmation No.: Unknown

Filed: 17 February 2000

For: HIGH MOISTURE VAPOR TRANSMISSION RATE FOAM./FILM COMPOSITE

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Remarks

The Office Action mailed 12 October 2001 has been received and reviewed. Claims 3 and 24 having been amended, the pending claims are claims 1-35. Reconsideration and withdrawal of the rejections are respectfully requested.

Figure 1

A substitute Figure 1 is submitted herewith that includes reference numeral "19". Also submitted is a redline version of the substitute Figure 1 indicating the change.

The 35 U.S.C. §102 Rejection

The Examiner rejected claims 1-9, 11-16, 18, 19, 22-27, 29-32, 34 and 35 under 35 U.S.C. §102(b) as being anticipated by Rawlings et al. (U.S. Patent No. 5,409,472). This rejection is respectfully traversed.

Rawlings et al. do not specifically teach or suggest substantially nonswellable foams. That is, there is no teaching or suggestion of a foam *per se* that is substantially nonswellable (i.e., a foam in which there is little or no increase in volume upon absorption of water or saline, and hence, exudates from a wound). Although at column 6, lines 23-29, Rawlings et al. teach that distortion of the dressing as a result of potential dimensional changes in the absorbent layer (e.g., by expansion in liquid uptake) is not desirable, there is no teaching or suggestion that the foams *per se* are substantially nonswellable. Furthermore, although certain of the chemistries of the absorbent foams disclosed in Rawlings et al. may be substantially nonswellable, there is no teaching or suggestion of which ones to select.

The Examiner contends that because the chemistries of foams of Rawlings et al. overlap with the chemistries of Applicant's foam, they would necessarily have the same properties. With respect to the amount of swell, Applicant's Representatives respectfully disagree. It is respectfully submitted that this missing descriptive information must necessarily be present in Rawlings et al. such that one of skill in the art would recognize such a disclosure. That is, this

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rejection is only appropriate if there is at least a reasonable likelihood that one of skill in the art could have discovered or recognized which foams were substantially nonswellable without specific guidance. That is, the subject matter relied upon must be disclosed in a manner to place it in possession of the public. This is not the case here.

In support of this, the Examiner is directed to the Declaration of Mary M. Swenson in which she states that she obtained samples of foam made of HYPOL 2000 and HYPOL 2002 (described at column 7, line 37 of Rawlings et al.) from Dow and tested them according to the Swell Test described in Applicant's specification. These samples had swell values of at least 60% (one was 60% and one was 99%). Thus, even if some of the foams of Rawlings et al. could by chance be substantially nonswellable, selection of such materials would not be easily recognized by one of skill in the art.

Withdrawal of this rejection is respectfully requested.

The 35 U.S.C. §103 Rejection

The Examiner rejected claims 10, 17, 20, 21, 28, and 33 under 35 U.S.C. §103(a) as unpatentable over Rawlings et al. (U.S. Patent No. 5,409,472) in view of Ward (U.S. Patent No. 5,000,172). This rejection is respectfully traversed.

As discussed above, Rawlings et al. do not specifically teach or suggest substantially nonswellable foams. That is, there is no teaching or suggestion of a foam *per se* that is substantially nonswellable (i.e., a foam in which there is little or no increase in volume upon absorption of water or saline, and hence, exudates from a wound).

Ward does not provide that which is missing from Rawlings et al. That is, Ward does not teach or suggest substantially nonswellable foams in a medical article. Thus, withdrawal of this rejection is respectfully requested.

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Summary

It is respectfully submitted that the pending claims 1-35 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
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Date

March 12, 2002

CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that this paper is being deposited with the United States Postal Service as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on this 12th day of March, 2002.

By: _____

Name: Ann M. Muetting



APPENDIX A - SPECIFICATION/CLAIM AMENDMENTS
INCLUDING NOTATIONS TO INDICATE CHANGES MADE

Serial No.: 09/507,108

Docket No.: 54682US002

Amendments to the following are indicated by underlining what has been added and bracketing what has been deleted.

In the Claims

For convenience, all pending claims are shown below.

5ub
Cl 1. A medical article comprising a liquid-impervious, moisture-vapor permeable polymeric film having directly bonded thereto an absorbent, substantially nonswellable foam.

2. The medical article of claim 1 which has a dry moisture vapor transmission rate of less than about 2000 g/m²/24 hours at 38°C and 20% relative humidity.

3. (AMENDED The medical article of claim [2] 1 which has a wet moisture vapor transmission rate of at least about 3000 g/m²/24 hours at 38°C and 20% relative humidity.

4. The medical article of claim 3 which has a wet moisture vapor transmission rate of at least about 5000 g/m²/24 hours at 38°C and 20% relative humidity.

5. The medical article of claim 2 which has a dry moisture vapor transmission rate of less than about 1800 g/m²/24 hours at 38°C and 20% relative humidity.

6. The medical article of claim 5 which has a dry moisture vapor transmission rate of less than about 1500 g/m²/24 hours at 38°C and 20% relative humidity.

7. The medical article of claim 1 wherein the foam absorbs greater than 250% by weight

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aqueous saline solution when immersed in phosphate buffered saline containing 0.9 wt-% NaCl at 37°C for 30 minutes.

8. The medical article of claim 1 wherein the liquid-impervious, moisture-vapor permeable polymeric film has a dry moisture vapor transmission rate of at least about 300 g/m²/24 hours at 38°C and 20% relative humidity.
9. The medical article of claim 8 wherein the liquid-impervious, moisture-vapor permeable polymeric film has a wet moisture vapor transmission rate of at least about 3000 g/m²/24 hours at 38°C and 20% relative humidity.
10. The medical article of claim 1 wherein the liquid-impervious, moisture-vapor permeable polymeric film comprises one or more layers.
11. The medical article of claim 1 wherein the liquid-impervious, moisture-vapor permeable polymeric film is a thermoplastic polyurethane.
12. The medical article of claim 1 wherein the liquid-impervious, moisture-vapor permeable polymeric film has a thickness of about 10 microns to about 250 microns.
13. The medical article of claim 1 wherein the substantially nonswellable foam increases in volume by no greater than about 10% following a 30-minute soaking in phosphate buffered saline at 37°C.
14. The medical article of claim 13 wherein the substantially nonswellable foam increases in

Amendment and Response - Appendix A

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volume by no greater than about 5% following a 30-minute soaking in phosphate buffered saline at 37°C.

15. The medical article of claim 1 wherein the substantially nonswellable foam is an open cell foam.

16. The medical article of claim 15 wherein the substantially nonswellable foam comprises a polyurethane.

~~17.~~ The medical article of claim 1 wherein the liquid-impervious, moisture-vapor permeable polymeric film includes graphics printed thereon.

18. The medical article of claim 1 wherein the liquid-impervious, moisture-vapor permeable polymeric film extends beyond a periphery of the foam.

19. The medical article of claim 18 wherein the liquid-impervious, moisture-vapor permeable polymeric film includes an adhesive disposed on the surface to which the foam is bonded around the periphery of the foam.

~~20.~~ The medical article of claim 1 wherein a nonwoven, woven, or knit web is bonded to the moisture-vapor polymeric film on a surface opposite the surface to which the foam is bonded.

~~21.~~ The medical article of claim 20 wherein the moisture-vapor polymeric film is bonded to the nonwoven, woven, or knit web with a fibrous adhesive.

22. The medical article of claim 1 wherein the foam is cast directly on the film.

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23. The medical article of claim 1 which is a wound dressing.
24. **(AMENDED)** A medical article comprising a liquid-impervious, moisture-vapor permeable polymeric film having directly bonded thereto an absorbent, substantially nonswellable foam, wherein the article has a dry moisture vapor transmission rate of less than $2000 \text{ g/m}^2/24$ hours and a wet moisture vapor transmission rate of at least about $3000 \text{ g/m}^2/24$ hours, at 38°C and 20% relative humidity.
25. The medical article of claim 24 which has a wet moisture vapor transmission rate of at least about $5000 \text{ g/m}^2/24$ hours at 38°C and 20% relative humidity.
26. The medical article of claim 24 which has a dry moisture vapor transmission rate of less than about $1800 \text{ g/m}^2/24$ hours at 38°C and 20% relative humidity.
27. The medical article of claim 24 wherein the foam absorbs greater than 250% by weight aqueous saline solution when immersed in buffered saline containing 0.9 wt-% NaCl at 37°C for 30 minutes.
28. The medical article of claim 24 wherein the liquid-impervious, moisture-vapor permeable polymeric film comprises one or more layers.
29. The medical article of claim 24 wherein the substantially nonswellable foam increases in volume by no greater than about 10% following a 30-minute soaking in phosphate buffered saline at 37°C .
30. The medical article of claim 24 wherein the substantially nonswellable foam is an open

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cell foam.

31. The medical article of claim 24 wherein the liquid-impervious, moisture-vapor permeable polymeric film extends beyond a periphery of the foam.

32. The medical article of claim 31 wherein the liquid-impervious, moisture-vapor permeable polymeric film includes an adhesive disposed on the surface to which the foam is bonded around the periphery of the foam.

33. The medical article of claim 24 wherein a nonwoven, woven, or knit web is bonded to the moisture-vapor, polymeric film on a surface opposite the surface to which the foam is bonded.

34. The medical article of claim 24 wherein the foam is cast directly on the film.

35. The medical article of claim 24 which is a wound dressing.

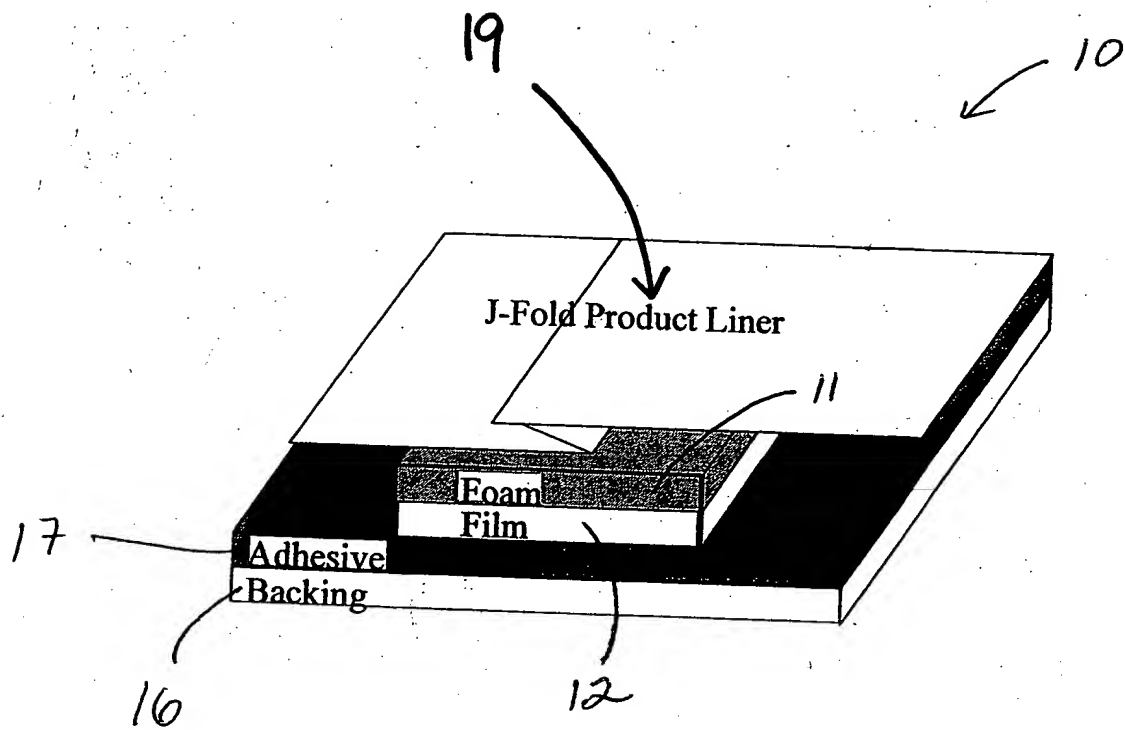


Figure 1

Substitute Figure 1 - Red-line copy